

Reconsideration of the above-identified application is respectfully requested in view of the following remarks.

### **REMARKS**

#### ***Status of the Claims***

Claims 1-16 and 30-32 are pending. Claims 1-16 and 30-32 have finally been rejected.

#### ***Rejections under 35 U.S.C. § 103***

(1) The Examiner has rejected claims 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Youssefych et al. (U.S. Pat. No. 5,968,519) in view of Lee (U.S. Pat. No. 5,552,162). Applicant respectfully traverses this rejection.

According to the Examiner, “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, such as hypertrophic scars such as taught by Lee within the methods of Youssefych.” See Office Action at page 5, third paragraph. Applicant respectfully disagrees with this conclusion.

#### **Claim 1**

Claim 1 is directed to, “[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.” See claim 1, as presently pending (emphasis added).

As the Examiner points out, Youssefeyh et al. is directed to the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, urticaria, psoriasis, erythema), gingivitis and acute injury. The Examiner further points out that Youssefeyh et al. teaches the use of topical formulations containing corticosteroids and a film-forming material, such as cellulose derivatives. However, Applicant respectfully points out that Youssefeyh et al. does not disclose or suggest a method for treating healed wounds so as to reduce scarring and/or improve the appearance of scars. In fact, the Examiner acknowledges this, stating that Youssefeyh “does not explicitly teach treatment of ‘healed wounds.’” See Office Action at page 4, third paragraph.

Nevertheless, according to the Examiner, “the methods of treatment and conditions to be treated as taught by Youssefeyh would include application upon healed wounds so as to reduce scarring and/or improve the appearance thereof.” See Office Action at page 4, third paragraph. The Examiner further states, “scarring, such as keloid formation, can occur as a result of inflammation, either mild or intense.” See Office Action at page 8. Applicant strenuously disagrees.

Again, Applicant respectfully points out that Youssefeyh et al. does not teach or suggest treating healed wounds to reduce scarring and/or improve the appearance of scars. Moreover, there is simply no indication whatsoever that the compositions disclosed in Youssefeyh et al. can be used for “treating healed wounds so as to reduce scarring and/or improve the appearance of scars,” as presently claimed.

Furthermore, Applicant respectfully asserts that the treatment of inflammation and pain associated with inflammatory dermatoses, gingivitis and acute injury, as taught and disclosed in Youssefeyh et al., is not the same as treating healed wounds so as to reduce scarring and/or improve the appearance of scars, as presently claimed.

Moreover, the methods taught by the present invention and those taught by Youssefeyeh et al., are directed to treating completely different conditions. Again, the former discloses a method to reduce scarring and/or improve the appearance of scars and the later teaches a method of treatment for inflammation and pain associated with inflammatory dermatoses. Inflammatory dermatoses is an inflammation of the skin, an immune response or reaction usually due to an external stimulus such as a sun burn, poison ivy, infection, etc. In contrast, scarring is a natural part of the body's healing process. A scar results from the biologic process of wound repair in the skin when the dermis layer is damaged. As part of the wound healing process, the body forms new collagen fibers to mend the damage. Occasionally, typically when the wound is particularly bad or deep, an overgrowth of collagen can occur, thereby resulting in scar formation. In most cases, scars typically form after a wound is completely healed. As such, Applicant respectfully points out that, scarring is not a form of inflammatory dermatoses, and likewise, inflammatory dermatoses is not a form of scarring. Rather, they are completely separate conditions with different causes, and more importantly, require different means of treatment.

Again, as previously pointed out, the presently claimed invention is directed to, "[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof." See claim 1, as presently pending (emphasis added). This method is not remotely taught or suggested by Youssefeyeh et al. Furthermore, Youssefeyeh et al. does not teach or suggest a method of treating a healed wound. Again, Applicant respectfully asserts that the disclosure of a method to treat

an inflammatory dermal condition does not in any way suggest treating healed wounds to reduce scarring or improve the appearance of scars. Moreover, there is simply no suggestion whatsoever, that the compositions disclosed in Youssefeyh et al. can be used for “treating healed wounds so as to reduce scarring and/or improve the appearance of scars,” as presently claimed.

The Examiner cites Lee to overcome the deficiencies of Youssefeyh et al. As the Examiner points out, Lee is directed to a method for improving the size and appearance of scar tissue. According to Lee, the method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. Lee also discloses the use of a therapeutically effective medicament with the thermal insulating material. Again, see Lee in the Abstract. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening that carrier into a tangible membrane juxtaposed to the healed wound to reduce scarring or improve the appearance of scars, as presently claimed.

Nevertheless, according to the Examiner, “Lee clearly resolves the deficiencies of Youssefeyh primary reference in their teaching of a method for improving the size and appearance of scar tissue associated with keloids or hypertrophic wound healing disorders.” See Office Action at page 8, first paragraph. The Examiner continues, “Lee amply describes and teaches such a method of treating scars whereby a hydrogel is applied to cover the scar and teaches the same elements, used for the same purpose as that desired by Applicant. Thus, the references, in combination, address the same method of treatment using the same process steps employed by Applicant.” See Office Action at page 8, first paragraph. Applicant respectfully disagrees.

Again, although Lee teaches a method for improving the size and appearance of a scar, Lee does not teach or suggest the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars, as presently claimed. Moreover, Applicant respectfully asserts that one of skill in the art would not look to the composition disclosed in Youssefeyh et al. to treat scar tissue. Again, there is simply no indication whatsoever in Youssefeyh et al. that the composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of scars. Again, scarring is not a form of inflammatory dermatoses, and likewise, inflammatory dermatoses is not a form of scarring. As such, Applicant respectfully asserts that one of skill in the art would not look to Youssefeyh et al. to improve the formulation disclosed in Lee for treating scars. There is simply no reason to combine elements of the composition disclosed in Youssefeyh et al., which teaches a composition for treatment of inflammation and pain, with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. Applicant respectfully points out that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some reason to do so.

Moreover, it is Applicant's position that one of skill in the art, without the benefit of Applicant's disclosure, would not be capable of arriving at the presently claimed invention. Applicant respectfully asserts that the Examiner is relying on Applicant's claim and/or disclosure to piece together elements to provide an argument for obviousness. Such piece-mealing together of elements is not permitted. Moreover, without looking to Applicant's specification there is simply no reason to combine the specific elements claimed (a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane

juxtaposed to the healed wound and using that composition to treat healed wounds to reduce scarring or improve the appearance of scars), from among the disclosures of Youssefeyeh et al. and Lee to come up with the presently claimed film. There is simply no suggestion whatsoever of the presently claimed combination in Youssefeyeh et al. or Lee.

As such, Applicant respectfully asserts that prior to Applicant's invention the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known. Furthermore, Applicant respectfully asserts that the combination of Youssefeyeh et al. with Lee does not and cannot render obvious the presently claimed invention. Reconsideration and withdrawal of this rejection are respectfully requested.

#### Claim 30

Claim 30 is directed to, "[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprising: applying onto a healed wound a topical composition comprising collagenase." See claim 30, as presently pending (emphasis added).

As previously pointed out, Youssefeyeh et al. does not teach or suggest a method of treating healed wounds to reduce scarring and/or improve the appearance of scars, as presently claimed. Again, as pointed out hereinabove, scarring is not a form of inflammatory dermatoses, and likewise, inflammatory dermatoses is not a form of scarring. Furthermore, Youssefeyeh et al. does not teach or suggest the use of a composition comprising collagenase to treat and/or improve scarring. In fact, there is no mention whatsoever in Youssefeyeh et al. of collagenase.

As previously pointed out, Lee is directed to a method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. However, there is no mention or suggestion whatsoever in Lee of including collagenase in a composition for treating and/or reducing scarring, as presently claimed.

As such, Applicant respectfully asserts that the combination of Youssefeyeh et al. with Lee does not teach or suggest all the claim limitations of claim 30, and thus, the combination cannot and does not render obvious claim 30. It is well settled that to establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. Likewise, claims 31-32, which depend from claim 30 are not rendered obvious. Reconsideration and withdrawal of this rejection are respectfully requested.

(2) The Examiner has rejected claim 1-16 and 30-32 under 35 U.S.C. §103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Lee (U.S. Pat. No. 5,552,162). Applicant respectfully traverses this rejection.

According to the Examiner, “Mantelle (‘070) teaches flexible, finite, bioadhesives compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents.” See Office Action at page 5, last paragraph. The Examiner continues, “[w]hile the prior art does not explicitly teach treatment of ‘healed wounds’, the prior art nonetheless explicitly teaches compositions that are topically applied on the skin for the effective treatment of pain. The method comprises applying a therapeutically effective amount of a

pharmaceutical agent, a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent in the carrier. The compositions are suitable for topical application on the skin.” See Office Action at page 6, fifth paragraph.

According to the Examiner, Lee teaches a method for improving the size and appearance of a scar associated with fibromatosis, a keloid or a hypertrophic wound healing disorder that comprises stimulating collagenase activity in the scar. The method comprises covering the scar with a hydrogel or thermally insulated material that elevates the surface temperature of the scar and that can contain a therapeutically effective amount of medicament.” See Office Action at page 6, last paragraph. The Examiner concludes, “[i]t would have been obvious to one of ordinary skill in the art at the time the invention was made to provide for methods for treating scars, particularly hypertrophic scars such as taught by Lee within the methods of Mantelle.” See Office Action at page 7, second paragraph. Applicant respectfully disagrees with this conclusion.

As previously mentioned, the presently claimed invention is directed to, “[a] method of treating healed wounds so as to reduce scarring and/or improve the appearance of scars comprises: applying onto a healed wound a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound thereby reducing scarring or improving the appearance thereof.” See claim 1, as presently pending (emphasis added). This method is not taught or suggested by Mantelle. Rather, as the Examiner points out, Mantelle is directed to a flexible, finite, bioadhesives compositions and methods for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents. Applicant respectfully points out that Mantelle does not teach



or suggest a method to treat healed wounds to reduce scarring or improve the appearance of scars. In fact, there is no mention or suggestion whatsoever in Mantelle that the composition disclosed therein can be used for treating a healed wound so as to reduce and/or improve the appearance of scarring. Examiner has acknowledged this, stating, "Mantelle does not teach treating a hypertrophic scar." See Office Action at page 6, second to last paragraph.

The Examiner cites Lee to overcome the deficiencies of Mantelle. As the Examiner points out, Lee is directed to a method for improving the size and appearance of scar tissue. According to Lee, the method for improving scarring comprises stimulating collagenase activity in the scar by applying a thermal insulating material that elevates the surface temperature of the scar. See Lee in the Abstract. Lee also discloses the use of a therapeutically effective medicament with the thermal insulating material. Again, see Lee in the Abstract. However, Lee does not teach or suggest the use of a fluid, film-forming carrier and hardening that carrier into a tangible membrane juxtaposed to the healed wound in method for treating healed wounds to reduce scarring or improve the appearance of scars, as presently claimed. Moreover, Applicant respectfully asserts that prior to Applicant's invention the use of a film-forming carrier to treat a healed wound to reduce scarring or improve the appearance of scars was not known.

Furthermore, Applicant respectfully asserts that one of skill in the art would not look to the composition disclosed in Mantelle to treat scar tissue. Again, there is simply no indication whatsoever in Mantelle that the composition disclosed therein can be used to treat healed wounds to reduce scarring or improve the appearance of scars. Furthermore, Applicant respectfully asserts that one of skill in the art would not look to Mantelle to improve the formulation disclosed in Lee for treating scars.

There is simply no reason to combine elements of the composition disclosed in Mantelle with elements of the composition disclosed in Lee, which teaches a composition for treating scar tissue. Applicant respectfully points out that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some reason to do so.

Moreover, it is Applicant's position that one of skill in the art, without the benefit of Applicant's disclosure, would not be capable of arriving at the presently claimed invention. Applicant respectfully asserts that the Examiner is relying on Applicant's claim and/or disclosure to piece together elements to provide an argument for obviousness. Such piece-mealing together of elements is not permitted. Moreover, without looking to Applicant's specification there is simply no reason to combine the specific elements claimed (a composition comprising a fluid, film-forming carrier, and subsequently hardening the carrier into a tangible membrane juxtaposed to the healed wound and using that composition to treat healed wounds to reduce scarring or improve the appearance of scars), from among the disclosures of Mantelle and Lee to come up with the presently claimed film. There is simply no suggestion whatsoever of the presently claimed combination in Mantelle or Lee.

As such, Applicant respectfully asserts that the combination of Mantelle with Lee does not and cannot render obvious the presently claimed invention.  
Reconsideration and withdrawal of this rejection are respectfully requested.

Respectfully submitted,

October 20, 2008  
Date

/Phillip R. Kiefer/  
Phillip R. Kiefer  
Reg. No. 55,326

Frenkel & Associates, P.C.  
3975 University Drive, Suite 330  
Fairfax, VA 22030  
Telephone: (703) 246-9641  
Facsimile: (703) 246-9646